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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,908	12/04/2001	Nissim Darvish	015/02481	3374
44909	7590	04/10/2006		
WOLF, BLOCK, SCHORR & SOLIS-COHEN LLP 250 PARK AVENUE NEW YORK, NY 10177				
			EXAMINER MANUEL, GEORGE C	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,908

Applicant(s)

DARVISH ET AL.

Examiner

George Manuel

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-81, 83 and 84 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-80 of copending Application No. 10/048,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to obvious variations of transporting a molecule in a desired manner and a non-excitatory control effect for controlling activity, and programming to achieve a desired provision of the molecule into a patient's vasculature.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 70, 75-77, 79 and 81-89 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Avitall '243. The implantable defibrillator through the electrodes 25 and 26 recognizes ventricular tachycardia or fibrillation. When defibrillation is indicated the implantable defibrillator discharges with approximately 30 joules via the two large patch electrodes 11 and 12 placed on the heart surfaces. In conjunction with this, the system will activate the pump 34 to deliver an amount of drug from the storage area to the anodic or positive patch electrode 11. Simultaneously, a small amount of current such as 1 mA/cm² adjusted to an amount below the capture threshold is delivered through the anodal patch in approximately 80-100 msec pulses synchronized with the ventricular depolarization. This iontophoretic current is delivered during the ventricular refractory so as to avoid any ventricular depolarization by the iontophoretic system.

Regarding claim 84, the drug delivery into the myocardium may occur at fixed intervals to sustain constant tissue concentration or in response to runs of ventricular tachycardia as recognized by the electrodes 25 and 26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance '081 in view of Lattin et al '609 and further in view of Aoki et al '397.

Chance teaches all of the claimed programming features. In addition, the examiner is interpreting the optical probe 14 to comprise a sensor for sensing a functional state of a non-cardiac tissue. Chance does not disclose the claimed features of the electric field transport device comprising drug delivery module 12. Lattin et al disclose the electrode structure that may be adaptable for use with drug delivery module 12. One of ordinary skill in the art would have found it obvious to combine the structural detail disclosed in Lattin et al for the drug delivery module 12 because Chance teaches the delivery device disclosed in Lattin et al may be substituted. See col. 7, line 59-63.

Chance in view of Lattin et al meet all of the claim limitations except for at least one of the electrodes comprising a pacing electrode.

Aoki et al teach an electrode used for iontophoresis may also be used for connecting bioelectrically stimulating devices such as pacemakers. One of ordinary skill in the art would have found it obvious to combine the teaching of Aoki et al with the electrode structure of Lattin et al because the Lattin et al electrode structure is intended to function for iontophoresis purposes.

Regarding claims 19, 36 and 63, one of ordinary skill in the art would have found it obvious to implant the electrode using a catheter because it is further well known in the pacing art to implant electrodes using a catheter.

Regarding claims 34, 40 and 41 the transport effect provided by the electrically induced transport may be either an excitatory or a non-excitatory field because Lattin et al teach the field produced may act on an agent that is either charged or uncharged.

Regarding claims 54 and 56, one of ordinary skill in the art would have found it an obvious modification to the electrode to shape it as either a spiral electrode or a mesh electrode because these shapes are well known in the pacing art.

Regarding claim 61, one of ordinary skill in the art would have found it an obvious modification to use a wireless electrode because Chance teaches the controller 16 includes a wireless interface and because the controller is connected by an RF coupler to drug delivery module 12.

Response to Arguments

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Chance teaches after comparing the received data with stored data, the controller 16 provides control signals for adjusting or discontinuing the drug delivery performed by drug delivery module 12. Lattin teaches a power source may include circuitry designed to permit the patient to manually turn the system on and off, such as with an on-demand medication regime, or to turn the system on and off at some desired periodicity, for example, to match the natural or circadian patterns of the body. A relatively simple controller or microprocessor could control the current as a function of time or could generate complex current waveforms such as pulses or sinusoidal waves. The control circuitry may also include a biosensor and some type of feedback system that monitors biosignals, provides an assessment of therapy, and adjusts the drug delivery accordingly.


Applicant's comment that pages 25 and 26 provide examples of non-excitatory control signals does not appear to negate the teachings disclosed in Chance.

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Lattin is not relied upon to teach signal frequencies operative to achieve pacing. Aoki et al teaches after this implanting, the element I is used as an electrical terminal for gathering bioelectrical signals or the like, or for connecting bioelectrically stimulating devices such as a pacemaker.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
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4/6/06